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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,073	03/19/2004	Saret Cornelis Hesseling	04148-00092	7907
22910	7590	11/16/2004	EXAMINER	
BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601			COMSTOCK, DAVID C	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/805,073

Applicant(s)

HESSELING ET AL.

Examiner

David Comstock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 12-40 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/047,433.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 19 March 2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-31 and 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michielli et al. (5,766,178; cited by applicant) in view of Jones et al. (3,908,201; cited by applicant).

Michielli et al. disclose a bone plug 10 having an elongate central body 22 of constant diameter and a plurality of equally spaced, flanges 14, 16. The flanges 14, 16 have a constant diameter but include a smaller diameter front flange 18. Michielli et al. also discloses flexing zones of decreased thickness (see, e.g. Fig. 3 and col. 3, lines 10-21). The flanges have a solid disk-like closed surface and the first flange is convex when it is inserted into a patient (see Fig. 4). The edges of the flanges are rounded about their circumference. The bore through the body is blind, at least with respect to the larger diameter bore, since the larger diameter bore, in order to not be blind, would have to continue through the body (see Fig. 1). However, the larger diameter bore does not do so and only a smaller diameter bore extending from the larger diameter bore extends through the body. The flanges include narrow radially perforated slots 17 (i.e. slits). Michielli et al. do not disclose forming the plug implant from

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polyethylene glycol terephthalate and an aromatic polyester or the blind grooves. Jones et al. disclose forming implants from polyethylene glycol terephthalate and an aromatic polyester to increase the surface energy of the implant and improve the strength of the bond between the implant and the body (see col. 1, lines 3-12, 35-43, col. 1, line 64 - col. 2, line 23, col. 2, lines 42-48, and col. 4, line 40 - col. 5, line 59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the implant of Michielli et al. of polyethylene glycol terephthalate and an aromatic polyester, in view of Jones et al., in order to increase the surface energy of the implant and improve the strength of the bond between the implant and the body. Moreover, it is noted that it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to include a copolymer in the amount of 20-90 wt.% or 50-80 wt.% of the polyethylene glycol terephthalate, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It is noted that the material is considered to be swellable since the material of the plug of the combination of Michielli and Jones et al. is the same material as that claimed by applicant. Regardless, selecting a swellable material of this type would involve nothing more than routine skill in the art, since, it has been held that selecting a known material on the basis of its suitability for the intended use

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involves nothing more than an obvious design choice. *In re Leshin*, 125 USPQ 416. It also would have been obvious to include any desired range of flanges, including at least four or at least five flanges, since it has been held that where the general conditions of a claim are disclosed in the prior art, i.e. a plug with a plurality of flanges, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michielli et al. (5,766,178; cited by applicant) in view of Jones et al. (3,908,201; cited by applicant) and further in view of Wiley et al. (5,263,991; cited by applicant).

The plug of the combination of Michielli et al. and Jones et al. discloses the claimed invention except for the blind grooves. Wiley et al. disclose a similar device 10 having blind grooves defined by the ridges 42, extending about the circumference and radially outward from the axis to the perimeter, in order to enhance positional stability and increase the safety and reliability of the device (see Figs. 2 and 3 and col. 4, lines 49-53). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plug of the combination of Michielli et al. in view of Jones et al. with blind grooves, in view of Wiley et al., in order to enhance the positional stability and increase the safety and reliability of the device.

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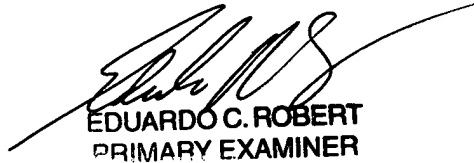
**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.



D. Comstock  
15 November 2004



EDUARDO C. ROBERT  
PRIMARY EXAMINER